Appl. No. 10/651,690 Dkt. No.112461-016

## **REMARKS**

#### 1. Status of the Claims

Claims 1-293 are pending in this application. Applicants have designated claims 278-287 as "not entered" as these claim numbers were inadvertently skipped when adding claims in the last office action reply. Applicants, in reply to a restriction/election requirement, elected to pursue, without traverse, claims of Group XVII. In the present office action, the examiner has withdrawn the restriction requirement of claims in Groups XIV and XVIII. Accordingly, claims 1-19, 28-69, 73-82, 86-137, 139-163, 165-175, 177-187, and 277-293 are to be considered first for prosecution on the merits. These claims stand rejected under 35 U.S.C. §§112, 102 (b), 102 (e) and 103 (a). These rejections are summarized in a table in the attached Appendix.

# 2. Claim Objection

The examiner has objected to claim 82. Applicants have amended claim 82 to depend from claim 73 instead of claim 37 to correct a transposition error. Applicants believe this amendment addresses the objection and respectfully request the objection be withdrawn.

## 3. Rejections Under 35 U.S.C. §112

The Examiner has rejected claims 1-19, 28-40, 43-52 and 277 under 35 U.S.C. §112, second paragraph (OA ¶7). Applicants have amended claim 1 to provide more detail to the steps taken in claim 1 and believe these amendments fully address this rejection and respectfully request a withdrawal of this rejection.

Appl. No. 10/651,690 Dkt. No.112461-016

The Examiner has rejected claims 38-40, 67-69, 80-82, 139-163, 165-175, 177-187, and 291-293, under 35 U.S.C. §112, first paragraph (OA ¶8) "as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention." The Examiner states that the characteristics of D2E7, CDP571 and CDP870 are not known. It is known to those skilled in the art that D2E7 is sold under the tradename HUMIRA (adalumumab). The properties of CDP571 and the method of making this compound are disclosed in U.S. Patent No. 5,994,510. Finally, the properties and method of making CDP870 are disclosed in U.S. Patent Application Publication No. US 2002/0151682 A1 (Athwal). Because the characteristics of these compounds are described in publicly available documents, Applicants submit the claims reciting these compounds are not indefinite, and, therefore, respectfully requests a withdrawal of the rejection of these claims.

The Examiner has rejected claims 38-40, 67-69, 80-82, 139-163, 165-175, 177-187, and 291-293, under 35 U.S.C. §112, first paragraph (OA ¶9, 10), "as failing to comply with the enablement requirement." The Examiner again states that the compounds D2E7, CDP571 and CDP870 must be known and readily available to the public. As stated above, D2E7 is readily available to the public as HUMIRA and the properties of the other compounds and their method of manufacture are detailed in publicly available documents. Accordingly, Applicants submit the present application is enabled for these compounds and respectfully request a withdrawal of the rejection of these claims.

## 4. Rejections Under 35 U.S.C. §102

The Examiner has rejected the claims, identified in the attached Appendix, under 35 U.S.C. §102 (b) in view of Chaouat et al. (J. Immunol., 1995, 154:4261-4268) (OA¶12).

Also, the Examiner has rejected the claims, identified in the attached Appendix, under 35 U.S.C. §102 (b) in view of Chaouat et al. (Cell Immunol., 1994, 157:328-340) (OA¶13).

Finally, the Examiner has rejected the claims, identified in the attached Appendix, under 35 U.S.C. §102 (e) in view of Pluenneke (US 2001/0021380 A1) (OA¶14).

Appl. No. 10/651,690 Dkt. No.112461-016

All of the claims under consideration in this Application have been amended to recite a step of administering a compound to a subject prior to conception by the subject. None of these three references recite this step. Accordingly, none of these references anticipate the claims as amended and, therefore, the Applicants respectfully request a withdrawal of these rejections.

# 5. Rejections Under 35 U.S.C. §103 (a)

The Examiner has rejected the claims identified in the attached Appendix in view of the combination of Pluenneke with other references identified in the Office Action (OA, ¶15-22). Pluenneke published on September 13, 2001 and claims priority to numerous applications the earliest of which was filed on April 19, 1999. The present application claims priority from a provisional patent application 60/406,804, which was filed on August 29, 2002. Because the publication date of Pluenneke is less than one year before the earliest effective filing date of the present application, Pluenneke is prior art under 35 U.S.C. §102 (e) and is not a statutory bar.

Applicants submit herewith a Declaration under 37 C.F.R. 1.131 by joint inventor Dr. Kwak-Kim averring that she conceived of the claimed invention prior to April 19, 1999, and worked on this matter diligently thereafter. Accordingly, Pluenneke should be excluded as a reference by virtue of this Declaration. Further, the Examiner cannot rely on Pluenneke in any combination, and, therefore, Applicants respectfully request a withdrawal of all the rejections under 35 U.S.C. §103 (a) as they all require Pluenneke..

#### 6. Conclusion

In view of the foregoing, Applicants submit the claims are in condition for allowance and respectfully request an early notice of the same.

Respectfully submitted,

**EVEREST INTELLECTUAL PROPERTY LAW GROUP** 

Date: August 31, 2005

Tin-Chuen Yeung, Reg. No. 40,240

P.O. Box 708

BY

Northbrook, IL 60065 Phone: (847) 272-3400